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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/759,731

01/16/2004

Christopher J. Bond

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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1639

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,731	<b>Applicant(s)</b> BOND, CHRISTOPHER J.	
	<b>Examiner</b> CHRISTOPHER M. GROSS	<b>Art Unit</b> 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 105-107,109-111,113-128 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1-7,9-12,15,16,18-24,29-34,36-40,42,44-46,48-54,59-66,68-74,76,81-85,90-96,98,99 and 105-130.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-7,9-12,15,16,18-24,29-34,36-40,42,44-46,48-54,59-66,68-74,76,81-85,90-96,98,99,108,112,129 and 130.

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### **DETAILED ACTION**

Responsive to communications entered 11/19/2008. Claims 1-7,9-12,15,16,18-24,29-34,36-40,42,44-46,48-54,59-66,68-74,76,81-85,90-96,98,99, 105-130 are pending. Claims 1-7,9-12,15,16,18-24,29-34,36-40,42,44-46,48-54,59-66,68-74,76,81-85,90-96,98,99,108,112, 129,130 stand withdrawn. Claims 105-107,109-111,113-128 are under consideration.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the prior application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994) [taken from MPEP 201.01]

The instant application, filed 1/16/2004 claims priority to provisional application 60/441,059 filed 01/16/2003 (referred to as '059) and claims benefit of provisional application 60/488,610 (referred to as '610) filed 07/18/2003 and claims benefit of provisional application 60/510,314 filed 10/08/2003.

Nevertheless, support for a CDRH3-phage coat fusion protein comprising a “N terminal portion of about 1 to 4 amino acids in which some or all amino acid positions are structural” and a “C terminal portion of about 1 to 6 amino acids in which some or all amino acid positions are structural” as set forth in amended claim 105 is not disclosed in the earlier applications.

It is further noted that support for a fusion protein comprising at least a portion of a phage coat protein is not supported in the earlier applications in that at least a portion reads on as little as one amino acid residue.

See also 35 USC 112 first paragraph considerations concerning new matter below.

Therefore 1/16/2004 remains the date for the purposes of prior art concerning claims 105-107, 109-111, 113-128.

*Response to Arguments*

N and C terminal Portions

On pp 20-21 of the response entered 11/19/2008, applicant alleges the examiner construes the N and C terminal portions as overlapping regarding the fusion protein set forth set forth in claim 105.

The examiner regrets any confusion raised in the last office action. The examiner was NOT suggesting that the N and C terminal portions overlap, but rather that claim 105 reads on for example, a fusion protein such as: NH<sub>2</sub>-Phage Coat Protein-SSSSNL<sub>20</sub>NSSS-COOH, where S is a structural amino acid; N is a non-structural amino acid and L are the central loop amino acids. On p 21 of applicant's remarks, applicant

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argues that the N terminus does not exceed 4 amino acids and the C terminus does not exceed 6 amino acids. In this vein it is noted this is not what claim 105 says. Claim 105 recites “a) N-terminal portion **of about** 1 to 4 amino acids in which some or all amino acid positions are structural; b) a C terminal portion **of about** 1 to 6 amino acids in which some or all amino acid positions are structural.” Emphasis added.

In response to applicant's argument, it is noted that the features upon which applicant relies (i.e., a N terminus [portion] which does not exceed 4 amino acids and a C terminus [portion] which does not exceed 6 amino acids) are not recited in the claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

At least a portion of a phage coat protein

For support of “at least a portion of a phage coat protein,” on p 21 of the remarks entered 11/19/2008, applicant attempts to points to p 72 line 28-p 73 line 1 of ‘610 which, in turn, attempts to incorporate by reference p 36 lines 23-24 of WO 93/191172 (referred to as ‘172 PCT). According to applicant the authors of ‘172 PCT displayed a scFv on the first amino acid of the fd minor coat protein.

In this regard, at least a portion of a phage coat protein constitutes essential material and according to MPEP 608.01(p) and 37 CFR 1.57(c) “Essential material” may be incorporated by reference, but **only by way** of an incorporation by reference to a **U.S. patent or U.S. patent application publication**, which patent or patent

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application publication **does not itself incorporate such essential material by reference.** Emphasis Added.

Here the present case may not itself through '610 incorporate essential material by reference and furthermore '172 PCT is neither a U.S. patent or U.S. patent application publication.

Nevertheless assuming arguendo that '172 PCT was a proper incorporation by reference, it is noted the passage cited by applicant prepares a scFv-pIII fusion protein including an *entire* fd (pIII) protein, not a portion thereof.

Accordingly 1/16/2004 remains the date for the purposes of prior art concerning claims 105-107, 109-111, 113-128.

### ***Withdrawn Objection(s) and/or Rejection(s)***

The objection to claim 122 is hereby withdrawn in view of applicant's persuasive arguments.

### ***Maintained Claim Rejection(s) - 35 USC § 102***

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 105-107, 109, 111, 113-128 are rejected under 35 U.S.C. 102(a) as being anticipated by **Bond et al** (2003 J. Mol. Biol. 332:643-655 – IDS entry 9/27/2004).

The claimed subject matter per claim 105 is drawn to a fusion protein comprising:  
at least a portion of a phage coat  
protein fused to a binding polypeptide comprising a heavy chain variable domain comprising a CDRH3 scaffold comprising: an N-terminal portion of about 1 to 4 amino acids in which some or all amino acid

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positions are structural; a C terminal portion of about 1 to 6 amino acids in which some or all amino acid positions are structural, and c)a central portion or loop of about 1 to 20 contiguous amino acids that can vary in sequence and in length.

Claims 106-107, 109,111,113-128 represent variations thereof.

**Bond et al** teach, through out the document and especially the abstract, structural contributions made by CDR3 loops in camelid V<sub>H</sub>H domains.

Said CDR3 loops in camelid V<sub>H</sub>H domains are taken as a CDRH3 scaffold, as set forth in claim 105 and defined in paragraph 0014 of the present published application (i.e. CDRH3 is the CDR3 of the heavy chain). Bond et al teach construction of a llama anti-human chorionic gonadotropin (alphaHCG) V<sub>H</sub>H fused to phage coat protein P3 on p 652, first paragraph. Bond et al teach in the paragraph bridging pp 644-645, the anti-alphaHCG structure comprises Trp 100 packing against Phe 37 and the aliphatic portion of Arg 45. Said Phe 37 and Arg 45 are taken as two structural amino acid positioned in the N terminal portion of claim 105. Said Trp 100 is taken as one structural amino acid positioned in the C terminal portion of claim 105. Bond et al teach on p 645 last paragraph insertions into said anti-alphaHCG at the short seven residue CDR3 loop, therein accommodating insertion of a central portion, reading on claim 105.

Bond et al teach in figure 1, camelid V<sub>H</sub>H domains may comprise a disulfide bond between residues Cys 33 and Cys 109, reading on claim 106.

Bond et al teach in the table in figure 4a, a V<sub>H</sub>H bearing a 17 residue insert comprising the sequence RIGR-...-WVTW (elected species) as an insert, reading on: R-L/I/MA<sub>3</sub>-R when A<sub>3</sub> is Gly, as set forth in claim 107; the R-I of claim 109; the W-V of claim 111; C terminal portion being 4 amino acids of claim 113; center portion being 9 amino acids of claim 114; R-L/I/MA<sub>3</sub>-R when A<sub>3</sub> is Gly and W-A7-A8-A9-A10-A11, wherein A7-11 can be any amino acid as set forth in claim 115.

Bond et al teach on p 649 second paragraph and figure 3b, shotgun alanine scanning as indicative of RI and WV being structural in said RIGR...WVTW insert, as set forth in claim 116-120.

Said WV is in positions 100i and 100j, according to figure 4a of Bond et al, as set forth in claim 121. Said figure 4a of Bond et al includes species bearing a central portion



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having at least one variant amino acid encoded by a non-random codon set as set forth in claim 122.

Said Phe 37 reads on the phenylalanine of claim 124 and hydrophobic residue of claim 123. Said Arg 45 reads on the arginine of claims 125 and 123. Bond et al teach Threonine at position 91 in figure 2, which appears to be in another framework region, reading on claim 126.

Said RIGR-...WVTW insert of Bond et al in figure 4a is 17 residues and reads on claim 128 when A1 is R, A2 is I, A3 is G, A4 is R, n is 9, A6 is S, A7 is W, A8 is V, A9 is T and A10 is W.

#### *Response to Arguments*

On p 22 of the remarks entered 11/19/2008, applicant argues that the present application is entitled to a priority date of at least 1/16/2003 based upon priority date of provisional application 60/441,059 thereby precluding Bond et al as prior art.

It is noted, however for the reasons set forth in the Priority Section above, the priority date for the present case 1/16/2004, hence the rejection is maintained.

#### ***Maintained Claim Rejection(s) – 35 USC § 112***

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 105-107, 109-111, 113-128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. This rejection concerns new matter.

Please note that this rejection has been modified from the original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Claim 105 is drawn to a CDRH3 fusion protein comprising at least a portion of a phage coat protein.

Claim 123 recites the residue at framework position 45 may be any hydrophobic amino acid.

Claim 126 recites another framework region.

The specification as originally filed provided no implicit or explicit support for a CDRH3 fusion protein comprising a portion of a phage coat protein.

The specification as originally filed provided no implicit or explicit support for the residue at framework position 45 being Ile Val, etc. (i.e. hydrophobic amino acids).

The specification as originally filed provided no implicit or explicit support for two framework regions.

Applicants are reminded that it is their burden to show where the specification supports any amendments to the disclosure. See MPEP 714.02, paragraph 5, last sentence and also MPEP 2163.06 I.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection

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based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not “new matter” is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

### *Response to Arguments*

On p 22-23 of the remarks entered 11/19/2008, applicant urges p 92, lines 11-16 of the present specification provide support for a CDRH3 scaffold with a N terminal portion is about 1 to 4 amino acids in which some or all amino acid positions are structural” and various other portions of the specification, especially p 100 lines 5-15 provide support for “at least a portion of a phage coat protein”

The examiner agrees applicant has successfully pointed to support for “...a portion of a phage coat protein...” and a “CDRH3 bearing a N-terminal portion of about 1 to 4 amino acids in which some or all amino acid positions are structural,” each *individually*. It is noted, however applicant has not successfully pointed to support for CDRH3 scaffold fused to at least a portion of a phage coat protein *together*, much less with all the other limitations set forth in claim 105.

On p 23 of the remarks entered, applicant urges that example 14 and in particular p 163 line 31 to p 164 line 4, referring to figure 52 provides support for any hydrophobic amino acid at position 45 as set forth in claim 123. It is noted however that example 14 recites Trp, Phe and Leu as preferred and does not indicate that other hydrophobic amino acids such as Val and Ile are interchangeable at position 45, as recited in claim 123. It is not clear how any hydrophobic residue is indicated in figure 52.

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On p 24 applicant urges that example 7 provides explicit support for "another framework region," as set forth in claim 126. Applicant asserts that residue 91 recited in claim 126 is in framework region 3.

In response to applicant's argument, it is noted that the features upon which applicant relies (i.e., framework region 3) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

#### ***Maintained Claim Rejection(s) – Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 105,107, 109,111,113,115-122,127-128 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 25,26,30,31,35-37,48-50 of copending Application No. 11/102502 (referred to as '502) in view of **Sidhu et al** (2000 J. Mol. Biol. 296:487-495 – IDS entry 9/27/2004) and evidenced by Bond et al (2003 J. Mol. Biol. 332:643-655 – IDS entry 9/27/2004) for the reasons set forth in the office action mailed 12/29/2006.

*Response to Arguments*

On p 27 of applicants remarks entered 11/19/2008, applicant once again requests that the provisional rejection be held in abeyance until allowable subject matter is indicated.

Applicants request has been considered, however the rejection will not be held in abeyance because the abeyance provision set forth in MPEP 804 applies to applications lacking rejections on other grounds and claim 105 at least of the present application stands rejected 35 USC 102 and 112 first paragraph as mentioned in the last office action. Therefore claims 105,107, 109,111,113,115-122,127-128 remain provisionally rejected on grounds of double patenting.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER M. GROSS whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571 272 0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross  
Examiner  
Art Unit 1639

cg

/ Christopher S. F. Low /  
Supervisory Patent Examiner, Art Unit 1639